

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### The effectiveness of Acceptance & Commitment Therapy on cognitive emotion regulation strategies, Anxiety, Depression, Headache Disability and Headache intensity in patients with Chronic Daily Headache

#### Protocol summary

##### Summary

The purpose of this study was to investigate the effects of Acceptance and Commitment Therapy on cognitive emotion regulation strategies, Anxiety, Depression, headache disability and headache intensity among patients with chronic daily headache. The study is one-centered, non-blinded, and two-grouped. The population of this study is comprised of all adults with chronic daily headache, referring to the neurology clinic of the Shahid Beheshti Hospital of Kashan City, during 2016. A total of 40 patients selected as the study sample and assigned into intervention and control groups by block randomization method (20 participants in each group). Inclusion criteria include having chronic daily headache according to the International Classification of Headache Disorders, 3rd edition; informed consent to participate in the study and having old above 18. Major exclusion criteria include unwillingness to continue participation; having a medical diagnosis of organic brain disorder or psy-choitic disorder, having a history of psychological treatment during the preceding six months. The intervention group was trained for eight 90-min weekly group sessions. Cognitive emotion regulation Questionnaire (CERQ), Depression anxiety stress scale (DASS-21), Diary scale for headache and Headache related disability inventory (HDI) have administered at pretreatment and post-treatment in both groups. By comparing the mean scores of the two groups, the effectiveness of Acceptance and Commitment Therapy on cognitive emotion regulation strategies, Anxiety, Depression, headache disability and headache intensity determines in patients with chronic daily headache.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017091236145N1**

Registration date: **2017-11-20, 1396/08/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-11-20, 1396/08/29

##### Registrant information

###### Name

Hassan Khazraee

###### Name of organization / entity

Kashan university of medical science

###### Country

Iran (Islamic Republic of)

###### Phone

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###### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Kashan University of Medical science

##### Expected recruitment start date

2016-12-20, 1395/09/30

##### Expected recruitment end date

2017-04-21, 1396/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effectiveness of Acceptance & Commitment Therapy

on cognitive emotion regulation strategies, Anxiety, Depression, Headache Disability and Headache intensity in patients with Chronic Daily Headache

**Public title**

The effectiveness of Acceptance & Commitment Therapy on cognitive emotion regulation strategies, Anxiety, Depression, Headache Disability and Headache intensity in patients with Chronic Daily Headache

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria included: having chronic daily headache according to the International Classification of Headache Disorders, 3rd edition (beta version), and tending to participate in the study exclusion criteria included: having a medical diagnosis of organic brain disorder or psychotic disorder and having a history of psychological treatments during the preceding six months.

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Kashan University of Medical Sciences

**Street address**

Qotb-e Ravandi Blvd

**City**

Kashan

**Postal code****Approval date**

2017-10-17, 1396/07/25

**Ethics committee reference number**

IR.KAUMS.MEDNT.REC.1396.53

**Health conditions studied****1****Description of health condition studied**

Chronic Daily Headache

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

cognitive emotion regulation strategies

**Timepoint**

pretreatment and posttreatment

**Method of measurement**

cognitive emotion regulation strategies (CERQ)

**2****Description**

depression and anxiety

**Timepoint**

pretreatment and posttreatment

**Method of measurement**

DASS-21 scale

**3****Description**

headache disability

**Timepoint**

pretreatment and 2 months after treatment

**Method of measurement**

headache disability inventory (HDI)

**4****Description**

headache intensity

**Timepoint**

pretreatment and 2 months after treatment

**Method of measurement**

diary scale of headache

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention Group (Acceptance and Commitment Therapy): Completion of Cognitive emotion regulation Questionnaire (CERQ), Depression anxiety stress scale (DASS-21), Diary scale for headache and Headache related disability inventory (HDI) before intervention; going through 8 sessions of Acceptance and

Commitment Therapy training one session a week; completion of Questionnaires after intervention.

**Category**

Behavior

**2**

**Description**

Control Group (No intervention): Completion of Cognitive emotion regulation Questionnaire (CERQ), Depression anxiety stress scale (DASS-21), Diary scale for headache and Headache related disability inventory (HDI) before intervention; no intervention; completion of Questionnaires after intervention.

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

neurology clinic of Shahid Beheshti Hospital of Kashan City

**Full name of responsible person**

Dr Reza Daneshvar Kakhki (neurologist)

**Street address**

**City**

Kashan

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

research committee

**Street address**

Qotb-e Ravandi Blvd

**City**

Kashan

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Kashan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Kashan university of medical science

**Full name of responsible person**

Dr zanjani

**Position**

PHD/ science Committee of clinical psychology

**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*